

Performance Assessment of Film Forming Barriers (Skin Sealants)

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ABSTRACT

PURPOSE: To review data assessing performance of film forming barriers (barrier films).

RATIONALE: Maintenance of healthy intact skin is a constant challenge to health care professionals caring for skin that is repeatedly exposed to moisture, irritants, and/or adhesive tape trauma. Film forming barriers are often used to treat or prevent skin breakdown resulting from these insults. However, very little information from well designed and controlled clinical evaluations documenting efficacy of these products exists in the literature. That information which is available suggests variable and/or questionable efficacy.¹

METHODOLOGY: During development of a new, non alcohol barrier film*, data were collected from numerous studies assessing performance of this new product and several commercially available control products. Assessments were made with the following tests:

- Cytotoxicity: Five products were tested for cytotoxicity using an industry standard mouse fibroblast (with agar overlay) method.
- Patient Comfort: A pain assessment model using freshly tape stripped wounds on healthy human volunteers was developed. Five products and a saline control were assessed with this model.
- Durability and Water Repellence: A model was developed to measure the ability of barrier films to prevent wash-off and wear-off of a harmless water soluble dye from the skin. Five products and a unprotected control were assessed with this model.
- Protection From Adhesive Tape Trauma: A model was developed utilizing repeated tape stripping of the skin of healthy human volunteers. Transepidermal water loss was used as an indicator of skin damage.² Five products and an unprotected control were assessed with this model.
- Compatibility with absorbent products: A model was developed using healthy human volunteers to test ability of barrier films to resist transfer from skin to diaper material. Impact on diaper absorbency was also assessed. One barrier film and three petrolatum based skin protectants were tested with this model.

RESULTS: Cytotoxicity of the products ranged from minimally cytotoxic to extremely cytotoxic. Pain potential of the products ranged from no pain to severe pain upon application to compromised skin. Durability of the products ranged from totally ineffective 24 hours after application to highly effective at even 4 days post application. Protection from adhesive tape trauma ranged from totally ineffective to highly protective compared to non protected controls. Transfer from skin to diaper material ranged from 0% to 69% and correlated inversely with diaper absorbency, which ranged from 98% to only 10%.

CONCLUSIONS: Film forming barriers differ considerably in composition, cytotoxicity and effectiveness. Though manufacturers may make claims of product safety and effectiveness, health care professionals must constantly challenge manufacturers to provide data substantiating these claims.

*3M™ Cavilon™ No Sting Barrier Film, 3M Health Care, St. Paul, MN

1. Omura and Anazawa, JWOCN, 21 #6: 251-256, 1994.

2. Pinnagoda, et al., Contact Dermatitis, 22: 164-178, 1990.

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Background

A film-forming barrier (barrier film) is a protective polymer dissolved into fast-drying carrier solvent. When applied to the skin, the carrier solvent quickly evaporates off, leaving the protective polymer behind on the skin. The following table summarizes the differences and similarities of five commercially available film-forming skin protectants.

Product	Polymer	Solvent
Smith & Nephew Skin Prep™	Butyl Ester of PVA / MA Copolymer	Isopropyl Alcohol
Mentor Shield Skin™ Protective Barrier	Modified Polyester & Acrylic Resin	Isopropyl Alcohol
Bard® Protective Barrier Film Wipe	50/50 n - Butyl & Iso-Butyl Methacrylate	Isopropyl Alcohol
AllKare™ Convatec Protective Barrier Wipe	50/50 n - Butyl & Iso-Butyl Methacrylate	Isopropyl Alcohol
3M™ Cavilon™ No Sting Barrier Film	Acrylates Terpolymer	Hexamethyl Disiloxane

When asked in focus groups which performance attributes are important in selecting a barrier film, the following attributes were identified by nurses as being “very important.”

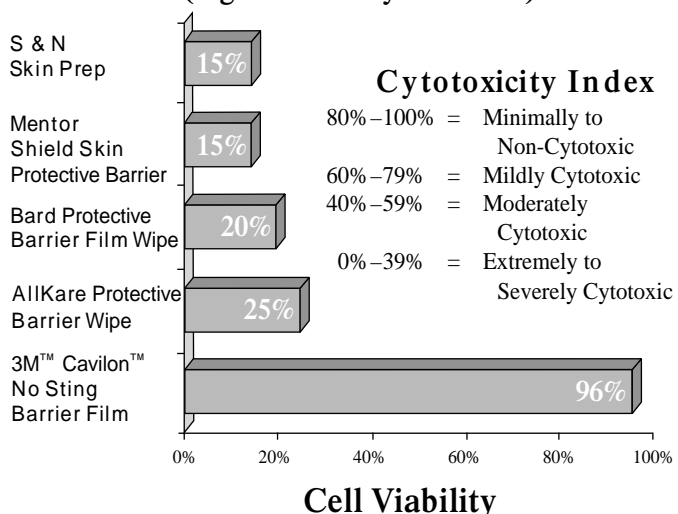
Performance Attributes

- Lack of Cytotoxicity
- Patient Comfort
- Barrier Effectiveness
- Protection from Skin Stripping
- Diaper Compatibility

Cytotoxicity

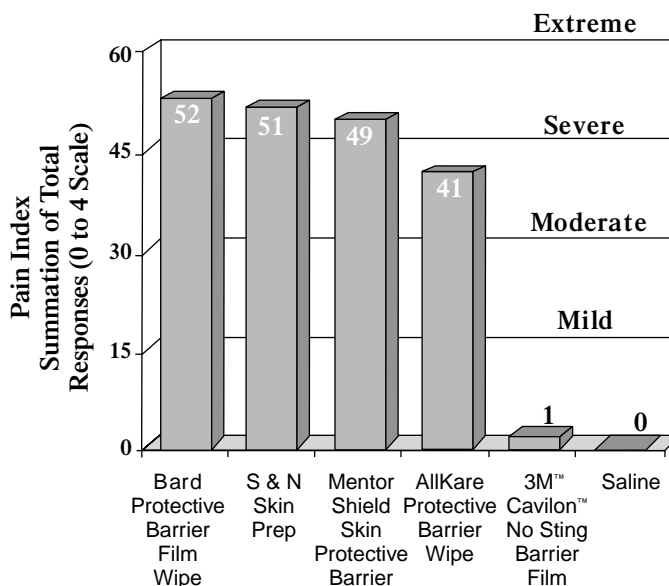
Skin barrier films are often used near wounds and over broken skin, the ideal product should be non-cytotoxic so as not to interfere with wound healing.

Mouse Fibroblast Cytotoxicity Assay (Agar Overlay Method)



Patient Comfort

A pain perception model was developed to test potential of film-forming barriers to cause pain when applied to compromised skin.

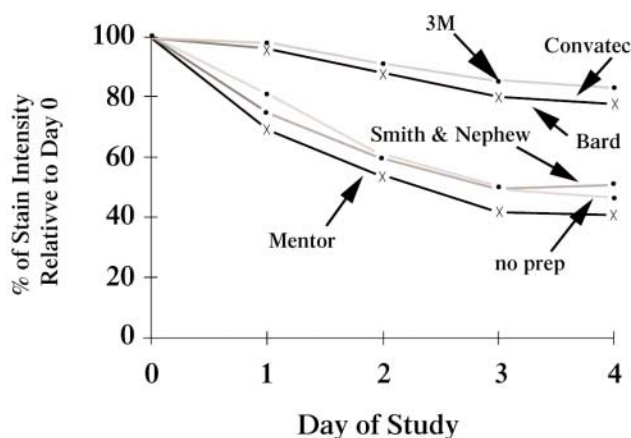


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Barrier Effectiveness

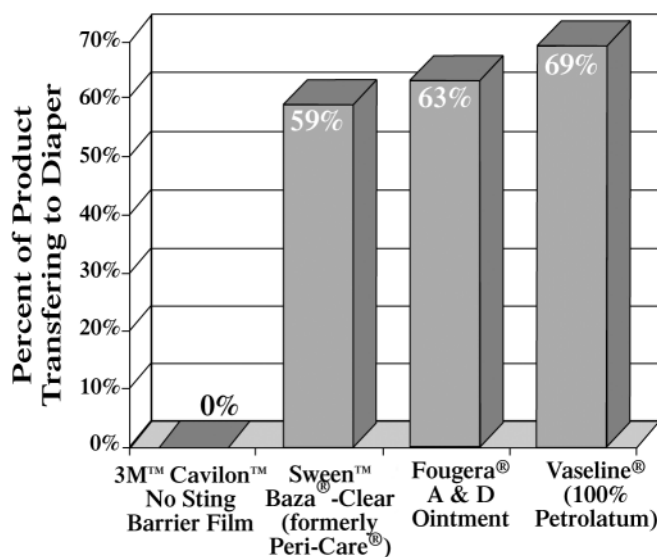
Barrier films are often used to protect skin from moisture and bodily effluents. A "Dye Retention Test" was developed to test abilities of film forming barriers to protect skin from moisture. Test products are applied over a harmless water soluble dye and subjects instructed to shower once daily. Intensity of the stains are measured daily.



Diaper Compatibility

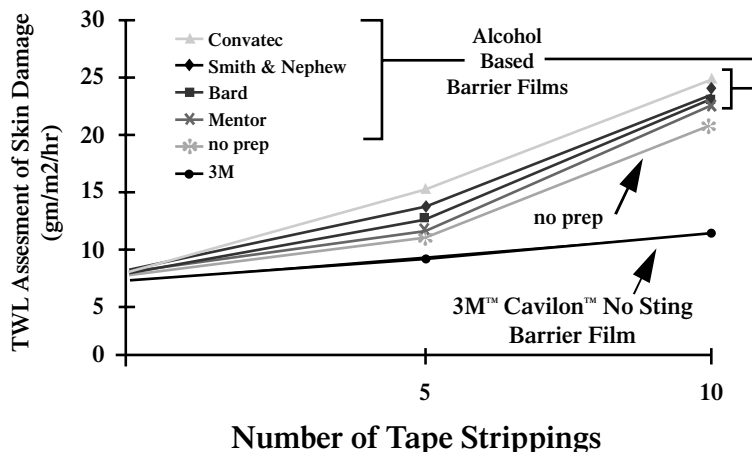
Moisture barriers are often used to protect skin exposed to urine and stool. Petrolatum based skin protectants are generally used in these situations. Anecdotal reports from users of petrolatum based ointments indicate the potential for diaper clogging. A model was developed to assess this potential.

Skin to Diaper Transfer

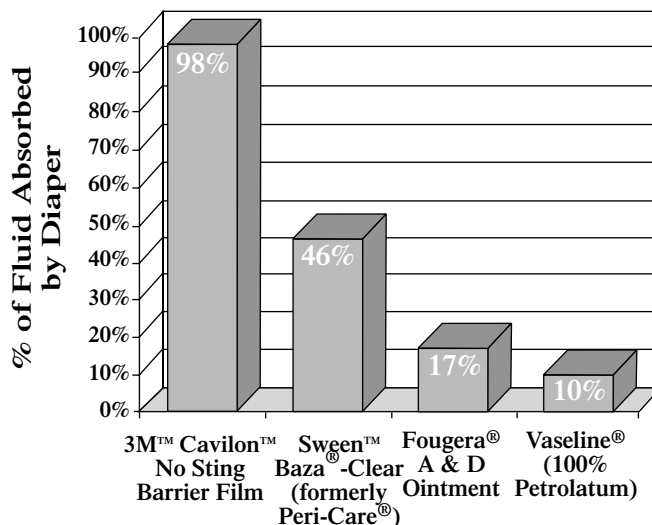


Protection from Skin Stripping

A model was developed to test ability of film-forming skin protectants to protect skin from adhesive tape trauma. Transepidermal Water Loss was used as a measure of skin damage.



Diaper Absorbency



Results

Cytotoxicity

3M™ Cavilon™ No Sting Barrier Film	=	Minimally Cytotoxic
Convatec AllKare™ Protective Barrier Wipe	=	Severely Cytotoxic
Bard® Protective Barrier Film Wipe	=	Severely Cytotoxic
Mentor Shield Skin™ Protective Barrier	=	Extremely Cytotoxic
Smith & Nephew Skin Prep™	=	Extremely Cytotoxic

Pain Potential on Compromised Skin

3M Cavilon No Sting Barrier Film	=	Pain Free
Convatec AllKare Protective Barrier Wipe	=	Moderately Painful
Bard Protective Barrier Film Wipe	=	Severely Painful
Mentor Shield Skin	=	Severely Painful
Smith & Nephew Skin Prep	=	Severely Painful

Moisture Barrier Effectiveness

3M Cavilon No Sting Barrier Film	=	Significant Protection 4 Days Post Application
Convatec AllKare Protective Barrier Wipe	=	Significant Protection 4 Days Post Application
Bard Protective Barrier Film Wipe	=	Significant Protection 4 Days Post Application
Mentor Shield Skin	=	No Protection 24 Hours Post Application
Smith & Nephew Skin Prep	=	No Protection 24 Hours Post Application

Compatibility With Diapers

3M Cavilon No Sting Barrier Film	=	Will Not Transfer or Clog Diapers
Convatec AllKare Protective Barrier Wipe	=	No Data (assumed to be compatible)
Bard Protective Barrier Film Wipe	=	No Data (assumed to be compatible)
Mentor Shield Skin	=	No Data (assumed to be compatible)
Smith & Nephew Skin Prep	=	No Data (assumed to be compatible)
<i><u>Petrolatum Based Ointments</u></i>		
Sween™ Baza® Clear (formerly Peri-Care®) Ointment	=	High Transfer Potential / Moderate Clogging Potential
Fougera® A & D Ointment	=	High Transfer Potential / High Clogging Potential
Vaseline®	=	High Transfer Potential / High Clogging Potential

Conclusion

Film forming barriers differ considerably in composition, cytotoxicity and effectiveness. Though manufacturers may make claims of product safety and effectiveness, health care professionals must constantly challenge manufacturers to provide data substantiating these claims.